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No. 06-1249

IN THE
Supreme Court of the United States

WYETH,
Petitioner,

v.

DIANA LEVINE,
Respondent.

On Writ of Certiorari to
the Vermont Supreme Court

BRIEF OF *AMICUS CURIAE* CONSTITUTIONAL AND ADMINISTRATIVE LAW SCHOLARS IN SUPPORT OF RESPONDENT

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Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989) 22

California Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272 (1987) 18

California v. ARC America Corp., 490 U.S. 93 (1989) 17

Christensen v. Harris County, 529 U.S. 576 (2000) 34

Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2nd Cir. 2006), *aff'd by an equally divided court*, 128 S. Ct. 1168 (2008) 23

English v. Gen. Elec. Co., 496 U.S. 72 (1990) 15

Exxon Corp. v. Governor of Md., 437 U.S. 117 (1978) 11

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) 36

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Garcia v. San Antonio Metro. Trans. Auth.,
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Geier v. Am. Honda Motor Co.,
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Gonzales v. Oregon,
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Gonzales v. Raich,
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Gregory v. Ashcroft,
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Halloran v. Parke, Davis & Co.,
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Mintz v. Baldwin,
289 U.S. 346 (1933) 4

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Pharm. Research and Mfrs. of America v. Walsh, 538 U.S. 644 (2003) 18

Rice v. Santa Fe Elevator Corp.,
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Rush Prudential HMO v. Moran,
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U.S. v. Mead Corp.,
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Will v. Michigan Dept. of State Police,
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21 U.S.C. §360k(a) 19

42 U.S.C § 282(d) 21

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Child Abuse, Domestic Violence, Adoption and Family Services Act of 1988, Pub.L. 100-294, 102 Stat. 102 (1988) 9

Defense of Marriage Act, Pub.L. 104-199, 110 Stat. 2419 (1996) 9

Elementary and Secondary Education Act of 1965, Pub. L. 89-10, 79 Stat. 27 9

Hearing Before a Subcomm. of the Comm. on Commerce of the U.S. Senate on S. 1944, 73d Cong. 2d Sess. 400, 403 (1933) 20

No Child Left Behind Act of 2001, Pub. L. 107-110, 115 Stat. 1425 (2001) 9

Pub. L. No. 110-85, 121 Stat. 823 (2007) 20

Pub. L. 110-85, Title VIII, § 282(d), 121 Stat. 922 (Sept. 27, 2007) 21

Pub. L. No. 87-781, §202, 76 Stat. 780, 793 (1962) 20

Reauthorization of the Prescription Drug User Fee Act: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 107th Cong. 49 (2002) (Rep. Waxman) 26

Religious Land Use and Institutionalized Persons Act of 2001, Pub. L. 106-274, 114 Stat. 803 (2000) 9

UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON GOVERNMENT REFORM – MINORITY STAFF, SPECIAL INVESTIGATIONS DIVISION, CONGRESSIONAL PREEMPTION OF STATE LAWS AND REGULATIONS at 1, 17-38 (2006) 20

Administrative Materials

63 Fed. Reg. 66378, 66384 (Dec. 1, 1998) 23

HHS, FDA, Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies, 73 Fed. Reg. 22158 (April 2008) 27

HHS, Office of Inspector General, *FDA's Monitoring of Postmarketing Study Commitments*, 8, 11-12 (June 2006)..... 28

Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (to be codified at 21 C.F.R. pts. 201, 208, 314, 601, 610) 35

Requirements on Content and Format of Labeling for Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000) 34

Other Authorities

2 FARRAND'S RECORDS 28 33

Armstrong, Timothy K., Chevron *Deference and Agency Self-Interest*, 13 CORNELL J.L. & PUB. POL'Y 203, 209-11 (2004) 33

Br. of *Amicus Curiae* Constitutional and Administrative Law Scholars in Support of Respts., No. 07-562, *Philip Morris USA Inc. and Altria Group, Inc. v. Good* (filed June 18, 2008) 5

Buzbee, William W., *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1574, 1585 (2007) 29, 33

Clark, Bradford R., *The Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1330 (2001) 7

Curfman, Gregory D., Stephen Morrissey, & Jeffrey M. Drazen, *Why Doctors Should Worry about Preemption*, N. ENGL. J. MED., July 3, 2008, at 3..... 30

Fontanarosa, Phil B., M.D., *et al.*, *Postmarketing Surveillance – Lack of Vigilance, Lack of Trust*, 292 J. AM. MED. ASS'N 2647, 2647 (2004) 26

Gardbaum, Stephen A., *The Nature of Preemption*, 79 CORNELL L. REV. 767, 806-07 (1994) 6

Gellhorn, Ernest & Paul Verkuil, *Controlling Chevron-Based Delegations*, 20 CARDOZO L. REV. 989, 992-94 (1999) 33

Government Accountability Office, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESSES 5 (March 2006) 25

Inst. of Med. of the Nat'l Acads., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 27 (Alina Baciu, Kathleen Stratton & Shelia P. Burke eds., 2006) 24, 25

Kesselheim, Aaron S., M.D., J.D. & Jerry Avorn, M.D., *The Role of Litigation in Defining Drug Risks*, 297 J. OF AM. MED. ASS'N 308, 308-309 (2007) 29

Kessler, David A. & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 468 & n. 27 ..... 20, 25, 30

Letter from Steven Rauschenberger, president, National Conf. of State Legis. to Michael Leavitt, secretary of HHS (Jan. 13, 2006) 32

McGarity, Thomas O. & Wendy E. Wagner, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH, 60-76, 85-87, 183-89, 246-51 (2008) 25

McGarity, Thomas O., THE PREEMPTION WAR 233 (forthcoming 2008) 29

Mendelson, Nina A., Chevron *and Preemption*, 102 MICH. L. REV. 737, 783 (2004) 32

Merrill, Thomas W., *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 758 (2008) 33

Merrill, Thomas W., *Rescuing Federalism After* Raich*: The Case for Clear Statement Rules*, 9 LEWIS & CLARK L. REV. 823 (2005) 7

Nelson, Caleb, *Preemption*, 86 VA. L. REV. 225 (2000) 10, 11, 12, 13

Porter, Margaret Jane, *The* Lohr *Decision: FDA Perspective and Position*, 75 FOOD & DRUG L.J. 7 (1997) 23, 35

Struve, Catherine T., *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 598 (2005) 24, 26

THE FEDERALIST NO. 10 (James Madison) 33

U.S. Dep't of Health & Human Servs., REPORT TO THE FDA COMMISSIONER FROM THE TASK FORCE ON RISK MANAGEMENT: MANAGING THE RISKS FROM MEDICAL PRODUCT USE – CREATING A RISK MANAGEMENT FRAMEWORK 30 (1999) 26

Vidmar, Neil & Valerie P. Hans, AMERICAN JURIES: THE VERDICT, 188-89, 327-31 (2007) 30

Vladeck, David C., *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 991 (2008) 34

Young, Ernest A., *Executive Preemption*, 102 NW. U. L. REV. 869, 883-89 (2008) 31

Constitutional Provisions

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Interest of Amici

Amici are scholars who teach and write about federal preemption of state law.[1] Mindful of the gap

[1] Counsel for all parties have consented to the filing of this brief, and those consents are on file with the Clerk of the Court. Pursuant to Rule 37.6, *Amici* affirm that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution to the preparation or submission of this brief, and that no person other than *Amici* and their counsel made such a monetary contribution.

that sometimes exists between the academy and the concerns of the bench and bar, we seek to bring our scholarship to bear on the particular preemption questions at issue in this case.

Our scholarly interest in preemption arises from teaching and writing in a variety of related fields, including constitutional law, administrative law, health law, and torts. Lynn E. Blais is a Professor of Law at the University of Texas School of Law, where she teaches Administrative Law. William W. Buzbee is a Professor of Law at Emory University School of Law, where he teaches Administrative Law. Philip Frickey is the Alexander F. & May T. Morrison Professor of Law at the University of California, Berkeley, School of Law, where he teaches Legislation and Constitutional Law. Thomas O. McGarity holds the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas, where he teaches Environmental Law and Torts. Paul E. McGreal is a Professor of Law at the Southern Illinois University School of Law, where he teaches Constitutional Law. Nina Mendelson is a Professor of Law at the University of Michigan Law School, where she teaches Administrative and Environmental Law. Theodore Ruger is Professor of Law at the University of Pennsylvania Law School, where he teaches Constitutional Law, Food and Drug Regulation, and Health Law. Neil S. Siegel is Associate Professor of Law at Duke Law School, where he teaches Constitutional Law. Wendy E. Wagner is the Joe A. Worsham Centennial Professor at the University of Texas, where she teaches Environmental Law and Torts. Ernest A. Young is a

Professor of Law at Duke Law School, where he teaches Constitutional Law and Federal Courts.

Summary of Argument

This case implicates three critical issues in the law of preemption. First, Petitioner's amici have launched a broad attack on this Court's longstanding "presumption against preemption," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), arguing that it is generally inconsistent with the original understanding of the Supremacy Clause and, in any event, inapplicable in conflict preemption cases. We argue, to the contrary, that the *Rice* presumption is not inconsistent with the original understanding of the Supremacy Clause, and it plays an essential role of protecting state autonomy in a world where national regulatory authority has been construed much more broadly than the Framers anticipated. Likewise, the claim that *Rice* does not apply to cases of conflict preemption misconstrues how conflict analysis actually operates and overlooks extensive precedent for such application.

The second issue concerns the preemptive effects of federal regulatory regimes that involve federal administrative approval of a product before that product can be marketed. There is no basis for construing federal premarket approval of drugs to preempt state common law liability for failures to warn. Despite a history of high profile tort litigation involving drugs, consistent efforts by industry to secure an express preemption clause similar to that in the Medical Devices Amendments (MDA), and recent statutory amendments to other aspects of the drug regime, the Food, Drug, and Cosmetic Act continues to include no express preemption provision.

Congress's evident desire to maintain state law as a supplement to federal regulation forecloses claims of conflict preemption as well. That desire is commendable, moreover, in light of serious doubts about the adequacy of the FDA's capacity to monitor drug safety after the initial approval of a drug.

Finally, this case implicates a broad set of issues concerning preemptive actions and interpretations by federal administrative agencies. This Court should accord little or no deference to the FDA's position that preemption is warranted. That position is a 180-degree reversal of the agency's longstanding view that state law provided a valuable supplement to federal regulation, and the new policy lacks the procedural indicia that this Court has generally required as a predicate to deference. Instead, the FDA's "preemption preamble" represents an effort to achieve tort reform by regulation following Congress's refusal to endorse such efforts. Congress's intent remains the touchstone for *all* forms of preemption, and that intent cannot support preemption here.

Argument

I. The Presumption Against Preemption Applies in This Case.

This Court first articulated a "presumption against preemption" in statutory construction in *Mintz v. Baldwin*, 289 U.S. 346, 350-52 (1933), and *Rice*, 331 U.S. at 229-36. The canonical statement occurs in *Rice*: "the historic police powers of the States [are] not to be superseded by [federal statute] unless that was the clear and manifest purpose of Congress." *Id.* at 230. Although Petitioner's *amici*

have challenged the *Rice* presumption's legitimacy and sought to narrow its scope, those arguments should be rejected.

A. The *Rice* Presumption Is a Critical Component of This Court's Federalism Jurisprudence.

We have articulated the case for a strong presumption against preemption at greater length in our *amicus curiae* brief in *Philip Morris USA Inc. v. Good*, which is also before the Court this Term.[2] We summarize those arguments briefly here. This Court's Commerce Clause jurisprudence leaves most areas of regulatory concern subject to concurrent national and state authority, with the result that the most critical federalism questions concern not so much what Congress *can* do, as a matter of constitutional power, but what it *has* done—and how much room it has left for state regulation. *Compare, e.g., Gonzales v. Raich*, 545 U.S. 1 (2005) (construing Congress's commerce power broadly to reach homegrown medical marijuana), *with Gonzales v. Oregon*, 546 U.S. 243 (2006) (construing the Controlled Substances Act *not* to authorize the Attorney General to preempt Oregon's Death with Dignity Act). Historically speaking, the *Rice* presumption developed as a response to the expansion of Congress's commerce power during the New Deal period: as the scope of Congress's action expanded, it was essential to ensure that federal

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[2] *See* Br. of *Amicus Curiae* Constitutional and Administrative Law Scholars in Support of Respts., No. 07-562, *Philip Morris USA Inc. and Altria Group, Inc. v. Good* (filed June 18, 2008). We incorporate the arguments of that brief here by reference.

activity did not displace too much state law. *See* Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 806-07 (1994).

Moreover, the *Rice* presumption fits well with this Court's recognition that structural and political safeguards play a critical role in protecting state autonomy against federal encroachments. *See Garcia v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528, 550-54 (1985). In *Gregory v. Ashcroft*, this Court explained:

> [I]nasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise. "To give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests."

501 U.S. 452, 464 (1992) (quoting Laurence Tribe, *American Constitutional Law*, § 6-25, at 480 (2d ed. 1988)). Requiring clear evidence of Congress's intent to alter the federal balance—whether by regulating the qualifications of state officers, as in *Gregory*, or by displacing state law through preemption—is important in two respects. It provides a *political* check, by providing notice to the States' representatives in Congress, and a *procedural* check, by requiring that state-displacing choices overcome

the Constitution's built-in hurdles to federal legislative action.[3]

As *Gregory* suggests, the *Rice* presumption is one of many rules of construction that protect state autonomy. *See, e.g.*, *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (requiring that Congress clearly state conditions on grants of federal funds to the States); *Jones v. U.S.*, 529 U.S. 848, 858 (2000) (requiring a clear statement of Congress's intent to regulate at the outer limits of its Commerce Clause authority); *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) (requiring a clear statement of Congress's intent to subject states to liability under federal statutes).[4] Because preemption questions arise so frequently, however, the *Rice* presumption is the most important of these rules.

This Court has sometimes—but not always—sought to limit the *Rice* presumption to fields that the States have "traditionally occupied." *Compare, e.g.*, *U.S. v. Locke*, 529 U.S. 89, 108 (2000) ("[A]n assumption of nonpre-emption is not triggered when the State regulates in an area where there has been a history of significant federal presence."), *with Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (stating that *Rice* applies "[i]n all pre-emption cases"). We think the *Medtronic* position is more workable, because competent lawyers can almost

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[3] *See generally* Bradford R. Clark, *The Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1330 (2001).

[4] *See generally* Thomas W. Merrill, *Rescuing Federalism After* Raich*: The Case for Clear Statement Rules*, 9 LEWIS & CLARK L. REV. 823 (2005).

always characterize a case as falling within a traditional field of national *or* state regulation to suit their purposes. Here, for example, Petitioner asserts that *Rice* does not apply because "[r]egulation of drug labeling has now been the domain of the Federal Government for more than a century," Petr.'s Br. at 51 n.23. But this Court has characterized its prior decision in *Medtronic*—which also involved FDA oversight of safety—as a "case involving medical negligence, a subject historically regulated by the States." *Locke*, 529 U.S. at 108. It was precisely this difficulty in defining boundaries between national and state fields of authority that led this Court to give up its restrictive reading of the Commerce Clause after 1937.

The truth is that medical drugs and devices—like virtually every other field of regulation—have seen a significant presence of *both* state and federal regulators for some time now. Prior 2002,[5] the FDA took the position that its approvals of drugs did *not* preempt traditional state regulation through the tort system. *See infra* at Part II(B) & fn.18. If a significant history of state regulation is enough to trigger the presumption against preemption, then this case fits the bill. If a significant *federal* presence suffices to oust the *Rice* rule, then that rule can have virtually *no* remaining applications.[6] *But see Bates*

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[5] *See Amicus* Br. for U.S. in support of Defendant-Appellant (Sept. 10, 2002), *Motus v. Pfizer, Inc.*, 358 F.3d 659 (2004), 2002 WL 32303084; *see* Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C.L. REV. 1089, 1094 n. 32 (2007_.

[6] *Cf. Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) ("Undoubtedly, every subject that merits

v. Dow Agrosciences LLC, 544 U.S. 431, 437, 449-450 (2005) (applying the presumption to preemption analysis under the Federal Insecticide, Fungicide, and Rodenticide Act's "comprehensive regulatory scheme"). After all, the Federal Government is significantly—but hardly exclusively—involved in almost every field, from family law,[7] to primary education,[8] to land use regulation.[9]

B. The Longstanding *Rice* Presumption is Consistent with the Supremacy Clause.

Petitioner's *amici*—with the significant exception of the United States—would go further and hold the *Rice* presumption unconstitutional on the ground that it is inconsistent with the original understanding of the Supremacy Clause. This radical position is based in part on an account of the Clause's drafting history. Br. of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petr. ("Chamber Brief"), at 14-17. As Petitioner's *amici* demonstrate, the Constitutional Convention adopted the Supremacy Clause only after rejecting James Madison's proposal

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congressional legislation is, by definition, a subject of national concern.").

[7] *See, e.g.*, Defense of Marriage Act, Pub. L. 104-199, 110 Stat. 2419 (1996); Child Abuse, Domestic Violence, Adoption and Family Services Act of 1988, Pub. L. 100-294, 102 Stat. 102 (1988).

[8] *See, e.g.*, No Child Left Behind Act of 2001, Pub. L. 107-110, 115 Stat. 1425 (2001); Elementary and Secondary Education Act of 1965, Pub. L. 89-10, 79 Stat. 27.

[9] *See, e.g.*, Religious Land Use and Institutionalized Persons Act of 2001, Pub. L. 106-274, 114 Stat. 803 (2000).

for a "congressional negative" on state laws. However, to observe that the negative's opponents "viewed it as unnecessary once the Supremacy Clause had been included in the Constitution," *id.* at 17, is hardly to establish that the Supremacy Clause was meant to have an equally sweeping effect on state law. If anything, the Framers' rejection of the negative ought to cast doubt on the assertion that a federal administrative agency can effectively "negative" state law simply by promulgating a preamble in an interpretive regulation.

Petitioner's *amici*'s more substantial argument against the *Rice* presumption rests on an incomplete reading of an article by Professor Caleb Nelson. *See* Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000); *see* Br. of *Amicus Curiae* Product Liability Advisory Council, Inc., in Support of Petr. ("PLAC Brief"), at 13-15; Chamber Brief at 13-14, 18.[10] We respectfully disagree with some of Professor Nelson's conclusions, but we note that his conclusions, considered in their entirety, actually support Respondent's position in this case.

The Supremacy Clause provides that the Constitution, treaties, and federal statutes "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. ART. VI, cl. 2. Professor Nelson argues that the last phrase would have been understood by the Founding generation as a "*non obstante* clause," which were frequently

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[10] The other scholars cited in the Chamber's brief rely, to varying degrees, on Professor Nelson.

employed to overcome the ordinary presumption against implied repeals of prior law. Nelson, *supra*, at 237-44. He argues that *Rice*'s presumption against preemption is inconsistent with this understanding: "A general rule that express preemption clauses should be read 'narrowly,' . . . . is hard to square with the Supremacy Clause's *non obstante* provision." *Id.* at 293.

Professor Nelson notes that "[o]ne should not take this point too far," *id.* at 294, and he has no quarrel with the proposition that "judges should generally be 'reluctant to infer pre-emption.'" *Id.* at 293 (quoting *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 132 (1978)).[11] It seems fair to read Professor Nelson's argument as foreclosing only a presumption that would be far more rigid than the way this Court has traditionally applied *Rice*.[12] Moreover, as the language quoted above indicates, his argument is limited to *express* preemption cases. *See also id.* at 292. His originalist reading of the Supremacy Clause has quite different implications for cases of *conflict* preemption such as this one.

According to Professor Nelson, "the Supremacy Clause puts the doctrine of preemption within the same general framework as the traditional doctrine

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[11] The PLAC Brief's suggestion that Professor Nelson's research supports "a presumption *in favor* of preemption," PLAC Brief at 15, thus misrepresents his actual conclusions.

[12] Professor Nelson also acknowledges that, given the placement of the semicolon in the Supremacy Clause, "the *non obstante* provision might have been directed especially at state judges," *id.* at 260—not at this Court. *But see id.* at 258-59 (arguing that the Framers played fast and loose with punctuation).

of repeals," *id.* at 245-46, which held that a later law superseded an earlier one only where the two provisions were "repugnant" to one another, *id.* at 236 (quoting 1 William Blackstone, *Commentaries* 59 (1765)). The Supremacy Clause established a rule of *federal* priority rather than a temporal one, but "the Supremacy Clause's rule of priority matters only when state law is 'repugnant to' valid federal law; the rule of priority comes into play only when courts cannot apply *both* state law *and* federal law, but instead must choose between them." *Id.* at 251. Under this "logical-contradiction test," *id.* at 260, broad notions of "obstacle preemption" are unconstitutional, *see id.* at 265-90. "[C]ourts could no longer find preemption simply because they think that state law hinders accomplishment of the 'full purposes and objectives' behind a federal statute." *Id.* at 304.

It is understandable that Petitioner's *amici* do not invoke this latter aspect of Professor Nelson's argument—it would eviscerate their argument for conflict preemption in this and many other cases. But his anti-obstacle preemption conclusion is inextricable from his attack on the *Rice* presumption, upon which petitioner's *amici* do rely:

> To be sure, [the *Rice*] presumption makes some sense within the Framework that the Supreme Court has developed for preemption cases . . . . By telling judges to approach federal statutes with "the starting presumption that Congress does not intend to supplant state law," the Supreme Court offsets its own expansive formulations of

> "implied" preemption. The presumption thus operates as an artificial way to bring the courts' results closer to Congress's probable "pre-emptive intent." Still, the presumption is a second-best alternative to a broader overhaul of the Court's doctrine.

Id. at 290-91. If this Court accepts Nelson's invitation to reconsider the *Rice* presumption, it should also reconsider the breadth of its conflict preemption jurisprudence. Nelson's historical research provides no support, however, for doing one without the other.

Even if we take the *non obstante* argument in isolation, it is limited to overcoming the traditional canon disfavoring implied repeals. As the preceding section makes clear, however, the *Rice* presumption rests not on the implied repeals canon but rather on the evolving structure of our federalism. The presumption developed in response to the expanding scope of potential federal regulatory authority in the mid-20th century, which transformed our federalism from a regime of separate spheres to one of concurrent powers. And the presumption responds to the parallel shift from relatively vigorous judicial enforcement of constitutional boundaries to a primary reliance on political and procedural checks on national authority. Professor Nelson acknowledges that "[w]hile the *non obstante* provision tells courts not to apply the general presumption against implied repeals in preemption cases, it does not require them to discard their other tools of statutory interpretation." *Id.* at 294. This Court's federalism-based "clear statement" rules and

presumption against preemption, which developed long after the period examined by Professor Nelson, are among those "other tools". It makes little sense to apply a contemporary sense of the scope of Congress's regulatory authority but insist on a *circa*-1789 set of preemption rules.

C. The *Rice* Presumption Applies to Cases of Implied Conflict Preemption.

Petitioner's *amici* also contend that the *Rice* presumption "is simply inapplicable to cases involving conflict preemption." Chamber Brief at 27; *see also* PLAC Brief at 15-19. We are at a loss to understand why courts should be *less* willing to find preemption when Congress has addressed the matter directly than in conflict cases, where Congress has not articulated its preemptive intent. This would turn the whole point of the *Rice* presumption—to ensure that the States' representatives in Congress consider and resolve questions of preemption themselves—on its head. Unsurprisingly, this Court has never endorsed the proposition advanced by Petitioner's *amici*.

Any confusion concerning the application of *Rice* in conflict cases stems from a belief that conflict cases focus only on the functional interplay of state and federal law. But that is an incomplete description of what courts do in cases involving conflict preemption. As this Court has made clear, the basic inquiry in *all* preemption cases—including conflict cases—concerns the intent of Congress. *See, e.g.*, *Medtronic*, 518 U.S. at 485 ("'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case."). The *Rice* presumption helps divine this intent.

In some cases it will be quite difficult to distinguish interpreting a statute's *express* preemptive effect from determining its purpose and effect for conflict purposes. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 104 n.2 (1992) (plurality opinion) ("[O]ur pre-emption categories are not 'rigidly distinct'") (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79, n.5 (1990)). It thus makes little sense to have different interpretive rules for conflict and express preemption. To take one obvious example, Section 636 of the federal Cable Act expressly preempts state law that is "inconsistent with this Act." 47 U.S.C. § 556(c). State law is *expressly* preempted, in other words, if it *conflicts* with federal law. Which interpretive rule would Petitioner's *amici* apply to a statute like this one? Putting this sort of conundrum aside, there are any number of cases in which the justices of this Court have disagreed as to whether the preemption at issue is best described as express or conflict preemption. *Compare, e.g.*, *Gade*, 505 U.S. at 103 n.2 ("We cannot agree that the negative implications of the text, although ultimately dispositive to our own *analysis*, *expressly* address the issue of federal pre-emption of state law. We therefore prefer to place this case in the category of implied pre-emption."), *with id.* at 111-12 (Kennedy, J., concurring in the judgment) (arguing that the preemption at issue was better characterized as express).

The present case demonstrates two perennial interpretive issues that arise across a variety of conflict preemption cases, and the *Rice* presumption sheds helpful light on each. The first issue involves identifying the relevant statutory purposes. If

Congress has but a single purpose in enacting a law, then state regulation that goes further in pursuit of that purpose most likely will not conflict with Congress's intent. Congress frequently has multiple purposes, however, and those purposes will almost always trade off with one another to some extent. In this case, for example, Congress's purposes include both ensuring the safety of drugs and promoting their availability. In such circumstances, opponents of state regulation can *always* claim that Congress has struck a balance between these purposes, so that *any* additional state regulation will disrupt the federal regulatory equilibrium.

This generic form of the argument, however, proves too much. Instead, the courts must interpret the regulatory scheme to determine whether Congress really meant to lock in a specific balance among competing purposes, or whether Congress intended to permit state variation within some reasonable range so long as state law furthered the primary purpose of the federal scheme. The *Rice* presumption is as helpful a default in these circumstances as it is with respect to express preemption clauses. It suggests that federal legislation should rarely be construed to represent a fixed balance among competing purposes that excludes state variation. *See, e.g.*, *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in the judgment) ("A free wheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law.").

The second issue concerns the effect of a federal *ex ante* approval of a product on *ex post* state

regulation, frequently through the tort system. We take up the merits of this issue with respect to drugs in Part II, *infra*. Here, we simply note that this sort of issue requires a careful analysis of what Congress intended the federal approval process to accomplish, the extent of federal *ex post* safeguards built into the scheme and whether Congress intended those safeguards to be exclusive, and what concerns—if any—it meant to leave to state *ex post* regulation. Again, no incongruity arises from applying a default rule like the *Rice* presumption to resolve ambiguities in Congress' intent concerning these matters.

Not surprisingly, this Court has had little trouble applying *Rice* to claims of conflict preemption. In *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002), for example, this Court applied the presumption against preemption to reject a claim that state law conferred remedies on HMO participants that were inconsistent with ERISA's remedial scheme.[13] Likewise, this Court has applied a presumption against preemption under the National Labor Relations Act, even though "[t]he NLRA contains no express pre-emption provision." *Bldg. & Constr. Trades Council v. Associated Builders & Contractors of Mass./R. of the Metropolitan Dist. I., Inc.*, 507 U.S. 218, 224 (1993). And in *California v. ARC America Corp.*, 490 U.S. 93, 101-102 (1989), this Court invoked *Rice* in the course of rejecting an obstacle preemption claim under the

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[13] The dissent made clear that the preemption claim relied on "ordinary principles of conflict pre-emption." 536 U.S. at 401 (Thomas, J., dissenting).

federal antitrust laws.[14] There is simply no basis, in either logic or experience, for holding the presumption against preemption inapplicable to conflict cases.

II. FDA Approval of a Drug Does Not Preempt Supplementary State Regulation.

The effect of federal agency approvals of products and practices is a recurring issue, but that does not mean that all such approvals should be treated the same. This Court has held, for example, that premarket approval of medical devices by the FDA preempts state common law claims challenging the safety and effectiveness of such devices, *see Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), but it has refused such effect to the FDA's "substantial equivalence" approvals of such devices, *see Medtronic, Inc. v Lohr*, 518 U.S. 470 (1996). We argue in this Part that the FDA's premarket approval of a *drug* should not have preemptive effect for three reasons: First, the statutory regime for drugs lacks the explicit preemption provision enacted by

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[14] *See also Pharm. Research and Mfrs. of America v. Walsh*, 538 U.S. 644, 666 (2003) (plurality opinion) (applying the *Rice* presumption to a conflict claim under the Medicaid statute); *accord id.* at 681 n.4, 682 (Thomas, J., concurring in the judgment) (same); *Ca. Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 281, 288 (1987) (applying a presumption against preemption in the course of rejecting a claim that a state pregnancy discrimination statute conflicted with Title VII); *Hillsborough Cty., Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 716 (1985) ("Appellee must thus present a showing . . . of a conflict between a particular local provision and the federal scheme, that is strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation.").

Congress for devices and applied by this Court in *Riegel*. Second, *ex post* regulation by the state tort system provides a necessary supplement to FDA postapproval review of drug safety, in light of crucial limitations on FDA resources and data-gathering authority. Third, the FDA's recent policy reversal according new preemptive effects to its drug approvals is entitled to little, if any, deference from the courts.

A. Congress Has Conspicuously Declined to Preempt State Claims Concerning Drugs.

Although this Court's decision in *Riegel* seems to have posed a similar question to this case, Congress has made clear that the regulation of drugs is to be treated differently from that of medical devices under the FDCA. The MDA contains an express preemption provision: "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device; and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. §360k(a). *Riegel* held that this provision preempted a state tort action, but the Court acknowledged that "Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices," 128 S. Ct. at 1009.

There is no corresponding express preemption provision for drug approval under the FDCA. Congress has amended the FDCA numerous times

without adding any preemption clause, and state common law claims remain an important part of the regulatory scheme.[15]

Congress rejected a proposal to include a right of action for damages in the 1938 FCDA because "a common law right of action exists." *Hearing Before a Subcomm. of the Comm. on Commerce of the U.S. Senate on S. 1944*, 73d Cong. 2d Sess. 400, 403 (1933). And in the 1962 amendments, Congress even included a savings clause: "Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, §202, 76 Stat. 780, 793 (1962). Congress amended the FDCA again recently with the Food & Drug Administration Amendments Act of 2007 (FDAAA), and again chose not to enact a generally applicable express preemption provision, despite efforts by the pharmaceutical industry to obtain such a provision. *See* Pub. L. No. 110-85, 121 Stat. 823 (2007); David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 468 & n. 27 (2008) (noting the disappointment of counsel for the pharmaceutical industry) (hereinafter, "Kessler & Vladeck"). The absence of

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[15] This refusal to add a preemption provision to the statute governing drug regulation has taken place even as Congress has added preemption provisions to at least 27 laws since 2001. *See* U.S. HOUSE OF REPS. COMM. ON GOV'T REFORM – MINORITY STAFF, SPECIAL INVESTIGATIONS DIVISION, CONGRESSIONAL PREEMPTION OF STATE LAWS AND REGULATIONS, 1, 17-38 (2006).

such a provision in the FDAAA is not mere oversight on the part of Congress—the legislative record indicates that preemption implications were considered by Congress,[16] and, ultimately, Congress decided to expressly preempt only a very narrow category of state regulation. *See* Pub. L. 110-85, Title VIII, § 282(d), 121 Stat. 922 (Sept. 27, 2007) (preempting state registering requirements for certain clinical trials).

Nor has Congress granted the FDA authority to unilaterally alter the preemptive effect of its drug labeling regulation. The MDA expressly preempts "different" or "addition[al]" state law requirements and delegates to the FDA a specific role in determining the Act's preemptive reach, but nothing in the FDCA indicates that Congress intended FDA drug labeling regulation to have equivalent effect. Nor is there any provision conferring authority on FDA to make a determination as to when consistent but different or additional state requirements would be preempted. *Compare* 21 U.S.C. § 360k *with* 21 U.S.C. § 301, *et seq.*; *see also Medtronic*, 518 U.S. at 495-496 (discussing the FDA's unique role in determining the scope of § 360k's pre-emptive effect).

The stark textual disparity between this case and *Riegel* ought to require a different result. This Court has noted that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to 'stand by both concepts and to tolerate

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[16] *See* fn. 21 and accompanying text, *infra*.

whatever tension there [is] between them.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984)).[17] Petitioner's effort to achieve the same result as the MDA's express preemption clause on *conflict* preemption grounds in drug cases invites this Court to substitute its own policy judgment for that of Congress.

In any event, it is not difficult to postulate sound reasons why Congress treated drugs differently from devices. As the *Riegel* Court noted, the MDA was spurred by several states' adoption of premarket approval regimes in the wake of the Dalkon Shield failure. 128 S. Ct. at 1002. Although *Riegel* held that the textual sweep of the MDA's preemption clause encompassed common law claims as well, there is no dispute that state premarket regimes were the primary object of Congress's preemptive intent. *See also Medtronic*, 518 U.S. at 489 ("[W]hen Congress enacted §360k, it was primarily concerned with the problem of specific, conflicting state statutes rather than the general duties enforced by common actions."). Throughout the development of the FDCA's regime for drugs, by contrast, "no state regulations required premarket approval of the drugs or additives in question, so no preemption clause was needed as a check against potentially conflicting state regulatory regimes."

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[17] *See also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449-450 (2005) ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.").

Riegal, 128 S. Ct. at 1018 (Ginsburg, J., dissenting). The omission of an express preemption clause for drugs was thus no mere oversight, but rather a considered judgment that state law did not pose a threat to the federal regulatory regime in that area.

Moreover, the choice to preempt state common law regulation turns, at least in part, on the confidence that Congress has in the FDA's own capacity to monitor drug safety after drugs are approved and marketed. As the next section demonstrates, Congress had good reason to doubt that capacity in the case of drugs.

B. State Tort Litigation Provides a Valuable and Necessary Supplement to FDA Review.

As Judge Calabresi recently noted, the issues in this case implicates the "considerable and undisputed" power of the states to protect consumers. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 86 (2nd Cir. 2006), *aff'd by an equally divided court*, 128 S. Ct. 1168 (2008). Prior to 2002, the FDA's position was that FDA approval and state tort liability operate independently, "each providing a significant, yet distinct, layer of consumer protection." Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997) (written by then chief counsel for the FDA) (hereinafter, Porter).[18] This shared authority, favored by the FDA

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[18] *See also* 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998) ("FDA's regulations establish the minimum standards necessary, but were not intended to preclude the states from imposing additional labeling standards.").

for nearly a century, allows state law to compensate for limits on the FDA's resources, offset the potential for agency capture, provide a monitoring system for those risks not anticipated at the time of FDA approval, react quickly to address such unanticipated dangers, and compensate injured parties.

The FDA's policy reversal occurred in the teeth of rising concerns about the FDA's oversight of drug safety. These concerns go both to the comprehensiveness of premarket trials and the FDA's capacity to conduct adequate postmarketing monitoring of drug safety. "Even if it is rigorously conducted, a process that focuses on prior approval inevitably will fail to capture all relevant information." Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 598 (2005). Premarket trials often do not reveal all of the potential risks posed by a drug; as a recent study by the National Academies' Institute of Medicine concluded, "[t]he approval decision does not represent a singular moment of clarity about risks and benefits associated with a drug." Inst. of Med. of the Nat'l Acads., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 27 (Alina Baciu, Kathleen Stratton & Shelia P. Burke eds., 2006) ("IOM Study"). This is particularly true when drug risks relate to "vulnerable populations," involve interaction with other medications, do not manifest for an extended period of time, or are rare among the general population (though perhaps common among a particular subset of the population). *See* IOM Study at 37-38. In fact,

growing evidence reveals that some pharmaceutical manufacturers have designed their premarket trials in ways that are more likely to produce favorable results; that some manufacturers have reported data from premarket trials to the FDA selectively or interpreted them in ways more favorable to their interests; and that the FDA's oversight process does not always catch these errors. *See, e.g.,* Thomas O. McGarity & Wendy E. Wagner, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH 60-76, 85-87, 183-89, 246-51 (2008).

Because of these limitations on premarket analysis, the FDA has mechanisms in place for postmarket monitoring of drugs. But a recent Government Accountability Office study concluded that the "FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket drug safety issues. The process has been limited by a lack of clarity about how decisions are made and about organizational roles, insufficient oversight by management, and data constraints." Government Accountability Office, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESSES 5 (March 2006) ("GAO Report"); Kessler & Vladeck, *supra*, at 470. Likewise, the Institute of Medicine study concluded that the FDA lacks the resources needed to accomplish its goals and that the obstacles to accomplishing those goals will only increase in the future. IOM Study at 36. As another report explains, "[t]he majority of FDA program resources are devoted to premarketing scientific risk identification and assessment and approval or nonapproval. Significant, but substantially fewer,

resources are devoted to postmarketing surveillance and risk assessment activities." U.S. Dep't of Health & Human Servs. (HHS), REPORT TO THE FDA COMMISSIONER FROM THE TASK FORCE ON RISK MANAGEMENT: MANAGING THE RISKS FROM MEDICAL PRODUCT USE – CREATING A RISK MANAGEMENT FRAMEWORK 30 (1999) (hereinafter, "HSS Report").[19] A recent internal survey of FDA reviewers in the Center for Drug Evaluation and Research (CDER) found that "some two-thirds of respondents were either '[n]ot at all confident' or only '[s]omewhat confident' that the CDER 'adequately monitors the safety of prescription drugs once they are on the market." Struve, *supra*, at 601 (citing Office of Inspector General, HSS, HHS Survey at question 45).

Much of the FDA's postapproval surveillance is accomplished through review of adverse event reporting; however, postmarketing reporting suffers from both underreporting and overreporting. Only a small fraction of adverse reactions are reported. *See Reauthorization of the Prescription Drug User Fee Act: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 49 (2002) (Rep. Waxman); Phil B. Fontanarosa, M.D., *et al.*, *Postmarketing Surveillance – Lack of Vigilance, Lack of Trust*, 292 J. AM. MED. ASS'N 2647, 2647 (2004). Despite this, postmarketing adverse event reporting overwhelms the FDA's ability to digest the information provided. *See* HHS Report at 58 (likening the FDA's system for managing the

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[19] Although the FDAAA increases the resources available to the FDA for postapproval surveillance, it also significantly increases the postapproval responsibilities that draw on those resources.

information to searching for the proverbial needle in the haystack).

Recent and well-publicized examples highlight the FDA's inability to single-handedly police the labeling of drugs after those drugs reach the market. In May of 1999, the FDA approved Vioxx for the treatment of arthritis pain. Although the preapproval studies did not show any increased risk of heart attack, Merck submitted data to the FDA in June of the following year disclosing a significant increased risk of heart attack in Vioxx users. The FDA did not approve a new warning relating to the increased cardiovascular risks associated with Vioxx until April of 2002, however, and did not initiate its own study of these risks until 2003. *See* the FDA's "Vioxx Questions and Answers" page, available at http://www.fda.gov/cder/drug/infopage/vioxx/vioxxQA.htm. Merck later withdrew Vioxx from the market after a second clinical trial confirmed the first and demonstrated a two-fold increase in risk of heart attack. The FDA's failure to take stronger and swifter action has been widely criticized.

Congress took steps to improve postmarketing monitoring of drug safety in the FDAAA in 2007. The new amendments expanded the FDA's authority to mandate postmarketing safety studies; however, the studies that the FDA was able to persuade drug companies to undertake under the former regime were generally not completed, and it is unclear if the new statute will improve on that record. *See* HHS, FDA, Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies; Availability, 73 Fed. Reg. 22157, 22158 (April 24, 2008) (as of September 2007,

71% of postmarketing study commitments for approved new drugs had not yet been started even though nearly half of those commitments were more than three years old; only 26% of outstanding postmarketing study commitments were either completed or proceeding on schedule).[20] Congress seems to have lacked confidence that the new amendments would obviate the need for state tort law. Not only did Congress eschew an MDA-like express preemption clause, but the FDAAA's expansion of FDA authority to mandate postmarketing labeling changes included a "Rule of Construction" stating that nothing therein affects the responsibility of manufacturers to "maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations)." 21 U.S.C. §355(o)(4)(I). The CFR sections specifically mentioned are the basis for a manufacturer's ability to change drug labeling when appropriate without prior approval from the FDA through the Changes Being Effected (CBE) process—the authority, in other words, that Respondent argues permits drug manufacturers to adjust their label in response to state tort rulings. Br. of Respt. at 37-43. The FDAAA's Rule of Construction thus accommodates the operation of state tort obligations.[21]

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[20] HHS, Office of Inspector General, *FDA's Monitoring of Postmarketing Study Commitments*, 8, 11-12 (June 2006) (noting sporadic compliance with postmarketing commitments).

[21] *See* 153 Cong. Rec. S11832, col. 3, S11833, cols. 1-2 (Sept. 20, 2007) (Sen. Kennedy); *id.* at S11834, cols. 2-3 (Sen. Leahy); *id.* at S11835, col. 3 (Sen. Durbin).

As the FDAAA suggests, the relationship between the FDA and state litigation in the context of policing drug labeling is symbiotic.[22] The FDA has an expertise and big-picture vantage point that juries may not possess; state litigation, on the other hand, serves a number of functions that the FDA is not well-suited to perform. For example, litigation provides an incentive for manufactures to monitor actively and remediate quickly any new or increased dangers posed by approved drugs. State tort litigation frequently unveils and highlights important but previously undisclosed information. *See* Aaron S. Kesselheim, M.D., J.D. & Jerry Avorn, M.D., *The Role of Litigation in Defining Drug Risks*, 297 J. OF AM. MED. ASS'N 308, 308-309 (2007) (collecting examples); *see also Bates*, 544 U.S. at 451 (noting a similar dynamic with respect to pesticide regulation). And litigation provides the sole source of compensation for parties injured by inadequately or improperly labeled drugs. *See* Thomas O. McGarity, THE PREEMPTION WAR 233 (forthcoming 2008) (tort verdicts spread risk among beneficiaries of a product such that, when risk-benefit analysis mandates the acceptance of certain risk at the agency level, the costs of that risk are spread among those who benefit from the product rather than being born solely by the unlucky victims).[23]

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[22] *See* William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1574, 1585 (2007) ("[T]he different actors and modalities of state common law litigation make it a critical, although only partial, antidote to predictable sorts of government failures.").

[23] Much skepticism of state tort law stems from concerns about lay juries. The evidence driving such concerns is generally

Developments in the drug approval process have increased the importance of state common law in drawing attention to the risks posed by marketed drugs and compensating victims of the failure to adequately disclose such risks. Drugs were historically approved in Europe before they were made available in the U.S., but new drugs are now most often approved and marketed in the U.S. before they have been vetted anywhere else in the world. *See* Kessler & Vladeck, *supra,* at 486. At the same time, drug recalls and withdrawals in the U.S. have been increasing. *See* GAO, FOOD AND DRUG ADMINISTRATION: EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 4 (2002). As the editors of the *New England Journal of Medicine* recently concluded, "[p]reemption will undermine the confidence that doctors and patients have in the safety of drugs and devices." Gregory D. Curfman, Stephen Morrissey, & Jeffrey M. Drazen, *Why Doctors Should Worry about Preemption*, N. ENG. J. MED., July 3, 2008, at 3.

C. The FDA's "Preemption Preamble" Warrants Little or No Deference.

This Court has been reluctant to decide the precise level of deference, if any, that courts owe to an agency's determination that the statute it enforces preempts state law. We believe that, as a general matter, deference to an agency's preemptive

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anecdotal: empirical work on jury verdicts in medical malpractice cases, by contrast, shows that jury verdicts reach comparable results to the judgments of medical professionals. *See* Neil Vidmar & Valerie P. Hans, AMERICAN JURIES: THE VERDICT, 188-89, 327-31 (2007).

interpretation of an ambiguous statute is inconsistent with the *Rice* presumption; moreover, federal agencies deciding preemption issues generally lack the comparative institutional competence advantages that they may enjoy with respect to other, more policy-oriented questions. *See generally,* Ernest A. Young, *Executive Preemption*, 102 NW. U. L. REV. 869, 883-89 (2008). In any event, the particular agency action at issue here—the FDA's so-called "preemption preamble"—is unworthy of deference under ordinary principles of administrative law.

1. Preemption is an inappropriate subject for deference generally.

The issue of deference to agency interpretation of statutes arises only when the underlying statute is ambiguous. In preemption cases, however, such ambiguity triggers the *Rice* presumption against preemption. This Court has never resolved the tension between its preemption jurisprudence and notions of administrative deference.[24] Most of the cases in which the Court has deferred to agencies on preemption questions involved agency findings of *no* preemption. *See, e.g., Sprietsma v. Mercury Marine*, 537 U.S. 51, 68-70 (2002); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495-96 (1996); *Hillsborough County,*

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[24] *Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1584 (2007) (Stevens., J., dissenting) ("[W]hen an agency purports to decide the scope of federal preemption, a healthy respect for state sovereignty calls for something less than *Chevron* deference."); *Medtronic*, 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part) ("It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference[.]").

Fla. v. Automated Med. Laboratories, Inc., 471 U.S. 707, 716-18 (1985). In such cases, the tension with *Rice* does not arise. In *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000), the Court did accord "some weight" to an agency's determination that state law was preempted, but it has never suggested that anything more than *Skidmore* deference, at most, is appropriate.

Courts should be particularly wary of deferring to an agency's determination of the preemptive effects of its regulations or governing statutes. Federal agencies do not represent the states, and their interests do not always align. *See, e.g.* Letter from Steven Rauschenberger, president, National Conf. of State Legis. to Michael Leavitt, secretary of HHS (Jan. 13, 2006) (complaining that the FDA's preemption preamble shows a "complete disregard for our dual system of government"). Indeed, agencies are notoriously unwilling to consider federalism values even where standing executive orders require them to do so. *See* Nina A. Mendelson, Chevron *and Preemption*, 102 MICH. L. REV. 737, 783 (2004) ("In 1999, the General Accounting Office reported that only five federalism impact statements had been prepared for the over 11,000 final rules agencies issued between April 1996 and December 1998.").

It is true, of course, that agency expertise will be valuable with respect to certain aspects of the preemption decision. But agencies have little comparative advantage with respect to the basic task of statutory construction. Preemption determinations require interpretations of both federal *and state* law, moreover, and federal agencies have no expertise with respect to the latter. *See*

Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 758 (2008) (hereinafter, "Merrill"). Likewise, a federal scientist's assessment of the likelihood of jury error in tort litigation is unlikely to be any better informed than that of the average layperson.

Deference to agency preemption determinations, moreover, makes the agency judge in its own case. Courts have long worried about trusting agencies to determine the scope of their own jurisdiction.[25] *See* Timothy K. Armstrong, Chevron *Deference and Agency Self-Interest*, 13 CORNELL J.L. & PUB. POL'Y 203, 209-11 (2004); Ernest Gellhorn & Paul Verkuil, *Controlling* Chevron*-Based Delegations*, 20 CARDOZO L. REV. 989, 992-94 (1999). The tendencies toward empire building and agency capture inherent in agencies are exacerbated by the ability to expand one's own power through preemption. *See* Merrill, *supra*, at 756; Buzbee, *supra*, at 1590 (identifying agencies' incentive to make themselves the sole locus of regulatory choice).

It is particularly ironic that Petitioner's *amici*, who begin by recounting the Philadelphia Convention's rejection of a congressional negative over state laws, end up endorsing an *executive* negative in the form of broad powers of agency preemption. To the extent that any "law that ought to be negatived will be set aside in the Judiciary department," 2 FARRAND'S RECORDS 28, this Court should make its preemption determination without

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[25] "No man is allowed to be a judge in his own cause; because his interest would certainly bias his judgment, and, not improbably, corrupt his integrity." THE FEDERALIST NO. 10 (James Madison).

undue deference to the agency's own self-serving views.

2. The FDA's "preemption preamble" lacks the indicia of deliberation, consistency, and persuasiveness necessary for deference.

The FDA's "preemption preamble" is not entitled to *Chevron* deference because it was not promulgated in the exercise of delegated authority to act with the force of law. *See, e.g.*, *U.S. v. Mead Corp.*, 533 U.S. 218, 229 (2001); *Christensen v. Harris County*, 529 U.S. 576, 586-87 (2000). Nor was the preemption preamble submitted for notice and comment; indeed, the initial notice of intent to revise the regulations affirmatively stated that the regulations would not preempt state tort claims. *See* Requirements on Content and Format of Labeling for Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000).[26]

Under *Mead*, the bases for deference to an agency decision include the formality, consistency, thoroughness, and persuasiveness of the agency's

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[26] *See also* David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 991 (2008) ("In the past, the FDA generally submitted its decisions on preemption policy to the rulemaking process, thereby subjecting the decision to public comment and ultimately to judicial review. The FDA is also required by Executive Order to give state and local governments notice and an opportunity to participate in any proceeding that may affect state or local law. The FDA did none of this with its new preemption position.").

view. *Mead*, 533 U.S. at 228. The FDA's preemption preamble is lacking in all of these dimensions. As noted above, the preemption preamble was adopted without a formal process and following statements by the FDA that the rules at issue would not preempt state tort actions. The FDA thus acted without receiving all expertise available on the issue.

Likewise, the FDA's preamble is inconsistent with its previous stance. For years previously, the FDA's considered judgment had been that state tort law is complementary to FDA drug regulation. *See, e.g.*, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998) ("FDA's regulations establish the minimum standards necessary, but were not intended to preclude the states from imposing additional labeling standards."); *see also* Porter, *supra*, at 11 ("The most important theme of this article is that the agency's position in *Lohr* and the Court's decision are the logical extensions of the agency's long-standing presumption against preemption in implementing section 521 of the [FDCA]."). In the absence of any explanation regarding how that change is grounded in changes in the industry, the new policy cannot be considered an instance of expert judgment. *Cf. Bates*, 544 U.S. at 449 (considering an agency's preemptive conclusion "particularly dubious" in light of its recent change in position).

The FDA's position also lacks persuasiveness because Congress knew of the FDA's consistent position that state tort laws were not preempted and took no action to change this treatment. State tort damage suits existed even before Congress passed the original FDCA in 1938. *See, e.g., Halloran v. Parke, Davis & Co.*, 245 A.D.727, 280 N.Y.S. 58

(1935); *Thomas v. Winchester*, 6 N.Y. 397 (1852). Yet, as described above, Congress has consistently refused to add a preemption provision concerning drug regulation to the FDCA.

This case is thus somewhat analogous to *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). In *Brown & Williamson*, the FDA had asserted jurisdiction over regulation of tobacco products after consistently stating that it had no such jurisdiction. One factor supporting the Court's conclusion that the FDA lacked such jurisdiction was Congress's acceptance of this position in passing other tobacco-regulating legislation and rejecting proposed legislation that would explicitly have given the FDA jurisdiction over tobacco regulation. Although Congress did not in this case pass legislation specifically in reliance on the FDA position against preemption, it has similarly refused to pass legislation overriding the FDA's position. This is strong evidence that the FDA's prior position was consistent with the intent of Congress.

Conclusion

The decision of the Supreme Court of Vermont should be affirmed.

Respectfully submitted,

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